

PATENT DOCKET 207,272

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT:** FERRARI ET AL.

**EXAMINER:**

**SERIAL NO.:** 10/553,582

**ART UNIT:**

**FILED:** October 17, 2005

**FOR:** PROCESS FOR PREPARING  
URSODEOXYCHOLIC ACID  
DI-SODIUM 3,7-DISULFATE

**Date:** February 8, 2006

**STATEMENT OF FILING BY EXPRESS MAIL 37 C.F.R. § 1.10**

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**INFORMATION DISCLOSURE STATEMENT**

**Honorable Commissioner for  
Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

**Sir:**

This Information Disclosure Statement (hereinafter sometimes referred to as "IDS") is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

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FEB 10 2006

(Check one of the boxes opposite A-D)

☐ A. within three months of the filing date of the above-identified national application or within three months of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in the above-identified international application.

☒ B. before the mailing date of a first office action on the merits.

☐ C. after the times set forth in (A) and (B) above, but before the mailing date of either a final action under 37 C.F.R. 1.113 or a notice of allowance under 37 C.F.R. 1.311, and the necessary statement pursuant to 37 C.F.R. 1.97(e) appears below (see box "i") or the necessary fee is enclosed (see box "ii" below).

(check one of the boxes opposite "i" or "ii" below)

☐ i. (check the applicable statement)

☐ I, the undersigned, hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I, the undersigned, hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

☐ ii. A check for the fee set forth in 37 C.F.R. 1.17(p), presently believed to be \$ 240.00, is enclosed.

☐ D. after the times set forth in (A), (B), and (C) above, but before payment of the issue fee, since Applicant petitions for the consideration of this Information Disclosure Statement by a petition enclosed herewith pursuant to 37 C.F.R. 1.97(d)(2), a check for the petition fee set forth in 37 C.F.R. 1.17(i), presently believed to be \$ 130.00, is enclosed, and the necessary statement pursuant to 37 C.F.R. 1.97(e) appears below:

(check the applicable statement)

☐ I, the undersigned, hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I, the undersigned, hereby state that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

2. In accordance with 37 C.F.R. 1.98(a)(1), this IDS includes a list on form PTO-1449 of all patents, publications, or other information submitted for consideration by the Office, incorporated into this IDS as an attachment hereto. Pursuant to 37 C.F.R. 1.98(b): (i) each U.S. patent listed is identified by patentee, patent number, and issue date; (ii) each foreign patent or published foreign patent application is identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application; and (iii) each publication is identified by author (if any), title, relevant pages of the publication, date, and place of publication. A legible copy of each document listed is attached and incorporated into this IDS, except that no copy of any U.S. patent application is included pursuant to 37 C.F.R. 1.98(a)(2)(iii) and except as explained below.

(check the boxes opposite A and/or B and fill in blanks, if appropriate)

☐ A. Document(s) \_\_\_\_\_ is (are) substantively cumulative to document(s) \_\_\_\_\_, and, in accordance with 37 C.F.R. 1.98(c), only a copy of each of the latter document(s) is (are) attached.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon for an earlier filing date under 35 U.S.C. 120:

[insert serial numbers and filing dates of prior applications]

These documents are identified by attaching hereto copies of the forms PTO-892 and/or PTO-1449 from the files of the prior application(s) and Applicant requests that they be considered and made of record in this application in accordance with 37 C.F.R. 1.98(d). Pursuant to 37 C.F.R. 1.98(d), copies of these documents need not be provided with this IDS.

(check paragraphs 3 and/or 4, if applicable)

[X] 3. Document **DE 196 42 875 A1** is not in the English language. In accordance with 37 C.F.R. 1.98(a)(3), 1.98(c), it is stated that:

(check the applicable statement(s))

[ ] English translation(s) of the document(s) \_\_\_\_\_ (or of the pertinent portions thereof) is (are) enclosed and, thus no concise explanation of their relevance is required, (see M.P.E.P., 609, p. 600-92).

[ ] English-language equivalent(s) of the document(s) \_\_\_\_\_ (or of the pertinent portions thereof) which is (are) in fact translation(s) of the document(s) is (are) enclosed.

[X] The attached English-language version of a search report or other action by a foreign patent office in a counterpart foreign application which cites document **DE 196 42 875 A1** and which indicates the degree of relevance found by the foreign office is submitted to satisfy the requirement for a concise explanation of the relevance of the document(s), (see M.P.E.P., 609, p. 600-93).

[X] A concise explanation of the relevance of document(s) DE 196 42 875 A1 is set forth as follows:

Copy of International Search Report for PCT/EP2004/050538.

[ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.

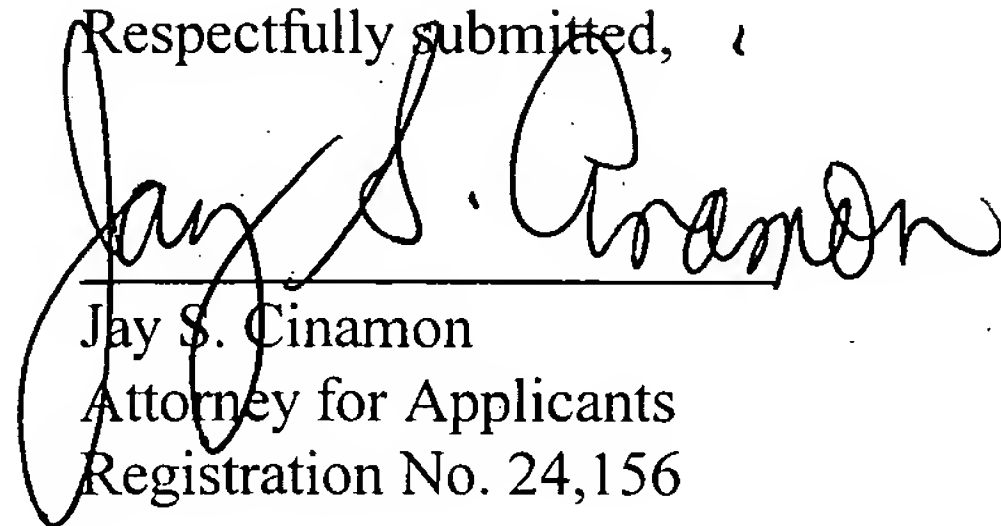
[ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on the attached sheet.

[ ] 4. Other information being provided for the Examiner's consideration follows:

5. In accordance with 37 C.F.R. 1.97(g), 1.97(h), the filing of this IDS shall not be construed as a representation that a search has been made or as an admission that information cited in this IDS is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b). Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

6. Please charge any deficiency or other fees or credit any refund or overpayment to Deposit Account No. 01-0035.

Respectfully submitted, 1

A handwritten signature in black ink, appearing to read "Jay S. Cinamon", is written over a horizontal line.

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wd\form ids

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|---|----|--|---|-------------------------------------|---|--------------------------|---|---|-----------------|-----------------------------|----------|----------|-------------------------------|---|
| Form PTO-1449<br>(Rev. 7-80)  |    | U.S. Department of Commerce<br>Patent and Trademark Office |   | Atty. Docket Control No.<br>207,272 |   | Serial No.<br>10/553,582 |   |   |                 |                             |          |          |                               |   |
| LIST OF RELATED ART CITED BY APPLICANT<br>(Use several sheets if necessary)   |    |  |   | Applicant<br>FERRARI ET AL.         |   |                          |   |   |                 |                             |          |          |                               |   |
|   |    |  |   | Filing Date<br>October 17, 2005     |   | Group                    |   |   |                 |                             |          |          |                               |   |
| U.S. PATENT DOCUMENTS   |    |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
| *Examiner Initial   |    | Document Number  |   |                                     |   |                          |   |   | Date            | Name                        | Class    | Subclass | Filing Date<br>If Appropriate |   |
|   | AA | 4  | 5   | 6                                   | 5 | 8                        | 1 | 1 | 1/21/86         | Di Schiena                  | A61K     | 31/56    |                               |   |
|   | AB | 3  | 2   | 7                                   | 1 | 2                        | 5 | 0 | 9/6/66<br>/     | Ken-Ichi<br>Kanazawa et al. | 167      | 65       |                               |   |
|   | AC | 3  | 8   | 3                                   | 6 | 5                        | 2 | 7 | 9/17/74         | Freisberg et al.            | C07C     | 173/00   |                               |   |
|   | AD |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AE |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AF |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AG |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AH |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AI |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AJ |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
| FOREIGN PATENT DOCUMENTS  |    |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   |    | Document Number  |   |                                     |   |                          |   |   | Date            | Country                     | Class    | Subclass | Translation<br>YES NO         |   |
|   | AL | 19   | 6   | 4                                   | 2 | 8                        | 7 | 5 | 23.4.98         | Germany                     | C07J     | 31/00    |                               | X |
|   | AM | W<br>O   | 97  | 1                                   | 8 | 8                        | 1 | 6 | 29.05.97        | WIPO                        | A61<br>K | 31/575   | X                             |   |
|   | AN |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AO |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AP |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
| OTHER RELATED ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   |    |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AR |  | Tozawa, Michiko "Sulfation of Steroids with Sulfamic Acid", Tokyo Joshi Ika Daigaku Zasshi (ABSTRACT), Vol. 83 (1), pgs. 104-6, 1968.   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   |    |  | Bandiera et al., "A Convenient Procedure for the Synthesis of Ursodeoxycholic Acid Sulfated Derivatives", Synthetic Communications, Marcel Dekker, Inc., Basel Vol. 17, No. 9, (1987) pgs. 1111-1117. |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AS |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   |    |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   | AT |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
|   |    |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |
| Examiner  |    |  |   |                                     |   |                          |   |   | Date Considered |                             |          |          |                               |   |
| *Examiner: Initial if reference considered, whether or not citation is in substantiation with MPBP and show the through citation if not in substantiation and not considered. Include copy of this form with next communication to applicant. |    |  |   |                                     |   |                          |   |   |                 |                             |          |          |                               |   |